DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10286 & CMS-10630]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed

collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use*: Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) the research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or

contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number*: CMS-10286, OMB control number: 0938-1077; *Frequency*: On Occasion; *Affected Public:* Private Sector; State, Local or Tribal governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 1. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460; *Use*: Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR 460.190 and 460.192 state that CMS, in conjunction with the State Administering Agency (SAA), must oversee a PACE organization's continued compliance with the requirements for a PACE organization.

The data collected with the data request tools included in this package allow CMS to conduct a comprehensive review of PACE organizations' compliance in accordance with specific federal regulatory requirements. The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM), as well as the SAA, to assess POs' compliance with PACE program requirements. If outliers or other data anomalies are detected, other offices within CMS will work in collaboration with MOEG for follow-up and resolution. Additionally, POs will receive

the audit results, and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS-10630 (OMB control number: 0938-1327); *Frequency:* Annually; *Affected Public*: Private Sector, State, Local, or Tribal Governments and Business or other for-profit institutions; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours:* 31,200. (For policy questions regarding this collection contact Kathleen Flannery at 410-786-6722.)

Dated: May 5, 2022.

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William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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